

TRACTION MASTERS, INC.
AKA SPINETRONICS, LLC
9737 NW 65TH PLACE
PARKLAND, FLORIDA 33076

MAR 21 2005



K042482

DR. DAVID B BASS, PRES. CELL: 516 426-9533
DR. SCOTT DENNY, V.P. CELL: 954 599-9766

510(k) summary

Company Name: Traction Masters, Inc. AKA: Spinetronics, LLC
9737 NW 65 PL
Parkland, Florida 33076

Telephone: 954-752-1994

Fax: 954-693-8834

Contact Person: David B Bass
Scott Denny

Date Prepared: September 8th, 2004

Trade Name: Bass Antalgic-Trak

Common Name: Powered Traction Table

Classification Name: Powered Traction Table (per CFR 890.5900)

Indications for Use

- 1) Patients with disc protrusions.
- 2) Patients with mild disc herniations.
- 3) Patients with pinched nerves.
- 4) Patients with limited spinal flexibility.
- 5) Patients with muscle spasms.
- 6) Patients with spinal vertebral fixations.
- 7) Patients with spinal facet imbrication and fixation.
- 8) Patients with spinal nerve root radiculitis.
- 9) Patients with foraminal encroachment.

Substantially Equivalent To:

The Bass Antalgic-Trak is substantially equivalent to products currently in commercial distribution. These include the:

- 1) The DRS System (K981822)
- 2) The Tru-Trak Traction Table (K8893448)
- 3) The Vax-D Therapeutic Table (K951622)
- 4) The Saunders 3-D activetrac (K001712)
- 5) The Jilco Traction Flexion Chair (K001361)



Device Description:

The Bass Antalgic-Trak is a multi-functional traction device. It is chair like in its appearance and patients get onto the unit as they would sit upon a chair or recliner. The chair/table can recline the patient 90 degrees. It maintains the patient's sitting posture during the recline. The Seat bottom is a vinyl covered dense foam. It measures 24 inches wide by 20 inches long by 3 inches deep backed by $\frac{3}{4}$ inch plywood. At the end of the seat bottom, at the knee joint, the seat bottom bends 30 degrees and continues as a calf support. The cushion continues 18 inches to support the calves. This seat-bottom section can manually rotate 80 degrees left or right, manually laterally tilt 35 degrees left or right, manually flex forward and backwards 45 degrees. The entire seat bottom can also slide forward or backwards 6 inches by engaging an electric actuator motor. This is to accommodate taller patients with longer thighs. There are 3 leather/vinyl straps that secure the patient to the seat bottom. Strap 1 secures over the iliac crests, strap 2 secures over the thighs and strap 3rd secures over the shins. The seat back of the chair is vinyl covered dense foam. It is 20 inches tall and 18 inches wide and 3 inches deep backed with $\frac{3}{4}$ inch plywood. The headpiece is vinyl covered dense foam. It is 12 inches tall by 8 inches wide and 4 inches deep backed by $\frac{3}{4}$ inch plywood. It is mounted to the upper portion of the chair's top frame. The headpiece has a vinyl strap to secure the forehead onto the headpiece. When reclined, the chair/table is 60 inches long. In the upright posture, the chair height is 60 inches tall. The seat-bottom lumbar traction is powered by an electric single-columned actuator motor. The headpiece cervical traction is powered by an electric single-columned actuator motor. The thigh extension of the seat bottom is powered by an electric single-columned actuator motor. The table/chair recline is powered by an electric single-columned actuator motor. The seat-bottom lumbar traction and the headpiece cervical traction may be powered manually using foot pedals. There are separate foot pedal for each. The traction can be "auto" cycled using the control panel. The thigh adjustment length and table/chair recline must be engaged using the control panel. The clinician must set all functions.

David B Bass,
Inventor of the Bass Antalgic-Trak
Traction Masters, LLC., AKA Spinetronics, LLC.
March 3, 2005



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAR 21 2005

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Dr. David Bass
President
Traction Masters, Inc.
9737 NW 65th Way
Parkland, Florida 33076

Re: K042482
Trade/Device Name: Bass Antalgic-Trak
Regulation Number: 21 CFR 890.5900
Regulation Name: Power traction equipment
Regulatory Class: II
Product Code: ITH
Dated: June 1, 2004
Received: September 13, 2004

Dear Dr. Bass:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

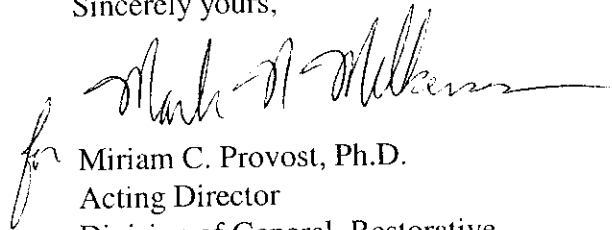
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 -- Dr. David Bass

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Miriam C. Provost", is written over the typed name.

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Bass Antalgic-Trak

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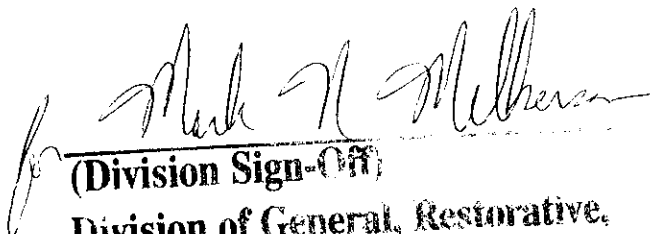
Prescription Use ☒
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

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510(k) Number

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